4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2340]

Matthew Hebert: Final Debarment Order

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Matthew Hebert for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Hebert was convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Hebert was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of May 5, 2021 (30 days after receipt of the notice), Mr. Hebert has not responded. Mr. Hebert's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at https://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa (ELEM-4029), Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits debarment of an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food. On December 11, 2020, Mr. Hebert was convicted, as defined in section 306(*l*)(1)(A) of the FD&C Act, in the U.S. District Court for the Northern District of Texas-Dallas Division, when the court accepted Mr. Hebert's plea of guilty and entered judgment against him for the offense of introduction of misbranded food into interstate commerce with intent to defraud and mislead, in violation of sections 301(a) and 303(a)(2) of the FD&C Act (21 U.S.C. 331(a) and 333(a)(2)).

FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: as contained in the superseding indictment, filed on January 5, 2016, Mr. Hebert was a co-owner of USP Labs with primarily responsibilities over product packaging design. As contained in the factual résumé submitted as part of Mr. Hebert's plea agreement on March 11, 2019, and the factual resumes submitted as part of plea agreements with his codefendants, one of Mr. Hebert's codefendants instructed a Chinese company to have 2 metric tons of ground cynanchum auriculatum root powder shipped internationally to S.K. Laboratories in California for inclusion in USP Labs' dietary supplement products, using the false name "cynanchum auriculatum root extract." USP Labs sent false labels to retailers and wholesalers listing "cynanchum auriculatum (root) extract" as an ingredient in OxyElite Pro "Advanced Formula" (which went on sale in or around August 2013), even though that ingredient was not present in the product. Beginning in or around August 2013, Mr. Hebert, USP Labs, and others working at USP Labs and S.K. Laboratories, did knowingly, and with the intent to defraud and mislead, cause the shipment of a misbranded food, namely the OxyElite Pro "Advanced Formula" dietary supplement, in interstate commerce.

Specifically, on or about October 4, 2013, with intent to defraud and mislead, Mr. Hebert caused the shipment of misbranded OxyElite Pro "Advanced Formula" in interstate commerce. The labeling for OxyElite Pro "Advanced Formula" falsely declared cynanchum auriculatum (root) extract as an ingredient, when in fact OxyElite Pro "Advanced Formula" contained imported cynanchum auriculatum powder but no cynanchum auriculatum (root) extract.

As a result of this conviction, FDA sent Mr. Hebert, by certified mail on March 29, 2021, a notice proposing to debar him for a period of 5 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Mr. Hebert's felony conviction of "introduction of misbranded food into interstate commerce with intent to defraud and mislead" in violation of sections 301(a) and 303(a)(2) of the FD&C Act constitutes conduct relating to the importation into the United States of an article of food because Mr. Hebert caused the shipment of a misbranded food in interstate commerce, and the food was misbranded because its labeling falsely declared cynanchum auriculatum (root) extract as an ingredient, when in fact the imported ingredient was cynanchum auriculatum powder, not cynanchum auriculatum root extract.

The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act, that Mr. Hebert should be subject to a 5-year period of debarment. The proposal also offered Mr. Hebert an opportunity to request a hearing, providing Mr. Hebert 30 days from the date of receipt of the letter in which to file the request, and advised Mr. Hebert that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Hebert failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Matthew Hebert has been convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food and that he is subject to a 5 year period of debarment.

As a result of the foregoing finding, Mr. Hebert is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective (see DATES). Pursuant to section 301(cc) of the FD&C Act, the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Matthew Hebert is a prohibited act.

Any application by Mr. Hebert for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2020-N-2340 and sent to the Dockets Management Staff (see ADDRESSSES). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at https://www.regulations.gov or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: July 23, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-16211 Filed: 7/29/2021 8:45 am; Publication Date: 7/30/2021]